

EXHIBIT A

Drugs Approved by the FDA

Document I-1

Drug Name: MetroLotion

The following information is obtained from various newswires, published medical journal articles, and medical conference presentations

Company: Galderma Laboratories

Approval Status: Approved November 1998

Treatment for: Dermatology

General Information

Treatment of inflammatory papules and pustules of rosacea.

Clinical Results

A controlled clinical study was conducted in 144 patients with moderate to severe rosacea, in which MetroLotion Topical Lotion was compared with its vehicle. Applications were made twice daily for 12 weeks during which patients were instructed to avoid spicy foods, thermally hot foods and drinks, alcoholic beverages, and caffeine. Patients were also provided samples of a soapless cleansing lotion and, if requested, a moisturizer. MetroLotion Topical Lotion was significantly more effective than its vehicle in the mean percent reduction of inflammatory lesions associated with rosacea and in the investigators' global assessment of improvement.

Side Effects

MetroLotion Topical Lotion is contraindicated in individuals with a history of hypersensitivity to metronidazole or to other ingredients of the formulation.

Also local allergic reaction, contact dermatitis, skin discomfort (burning and stinging), erythema and the following additional adverse experiences have been reported with the topical use of metronidazole: skin irritation, transient redness, metallic taste, tingling or numbness of extremities, and nausea.

Mechanism of Action

The mechanisms by which metronidazole acts in the treatment of rosacea are unknown, but appear to include an anti-inflammatory effect.

Drug listing last updated on June 20, 2008

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CenterWatch Newly Approved Drug Therapies Listing

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